K061372

MAY 30 2006

Section 2 510(k) Summary of Safety and Effectiveness

Date:	May 4, 2006
Submitter:	GE Healthcare Information Technologies 540 W Northwest Highway Barrington, IL 60010
Contact Person:	Karen M. Lunde Sr. Regulatory Affairs Leader GE Healthcare Information Technologies Phone: (847) 277-6092 Fax: (414) 755-0655
Device: Trade Name:	Centricity® AW Suite Option
Common/Usual Name:	Picture Archiving and Communications Systems and Workstation
Classification Names:	The Centricity PACS is classified as: 21 CFR 892.2050 System, Image Processing, Radiological The predicate advanced applications are classified as: 21 CFR 892.1750 Computed Tomography X-ray System (accessory to)
Predicate Device:	K043415: Centricity PACS System K993792: Smart Vessel Analysis Option K042694: Advanced Lung Analysis II Option K031871: AutoBone Option K041267: Card IQ Analysis III Option K041270: CT Colonography II Option K041521: Volume Viewer Plus Option
Device Description:	Centricity AW Suite is a software option that provides an interface between the Centricity Workstation (on a Windows platform) and Volume Viewer with advanced analysis options such that both these applications can run on a single platform while maintaining common patient and exam context. Volume Viewer is a previously FDA cleared image analysis software option. Optional advanced analysis extensions of the Volume Viewer application have been previously cleared by FDA and include AutoBone, Advanced Vessel Analysis, CT Colonography, CardIQ Analysis and Advanced Lung Analysis.
Intended Use:	Centricity AW Suite is an optional software package that provides an interface between the Centricity PACS Workstation and Volume Viewer such that both applications can run on a single platform while maintaining common patient & exam context. Optional advanced analysis extensions of the Volume Viewer application include: AutoBone, Advanced Vessel Analysis, CT Colonography, CardIQ Analysis, and Advanced Lung Analysis. Volume Viewer allows the processing, review, analysis and communication of 3D reconstructed images and their relationship to originally acquired images from CT, MR, X-Ray Angio, NM and PET Scanning devices. The combination of acquired images, reconstructed images, annotations and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery and treatment planning. Advanced Vessel Analysis can be used in the analysis of 3D angiography data. It provides a number of display, measurement and batch archive

features and will aid physicians in studying user-selected vessels for stenosis analysis, pre/post stent planning and directional vessel tortuosity visualization.

CardIQ Analysis allows the visualization of 2D and 3D medical image data of the heart derived from DICOM 3.0 compliant CT scans for the purpose of cardiovascular disease assessment. It provides functionality for 2D/3D rendering, assessment of calcified and non-calcified plaque to determine the densities of the plaque within a coronary artery, ventricular function of the heart, and measurement tools to detect coronary artery stenosis. This product can be used to aid a trained physician to process, render, review, archive and visualize cardiac anatomy and coronary vessels.

CT Colonography allows the visualization of 2D and 3D medical image data of the colon derived from DICOM 3.0 compliant CT scans for the purpose of screening of a colon to detect polyps, masses, cancers, and other lesions. It provides functionality for 2D/3D rendering, bookmarking of suspected lesions, synchronized viewing of the 2D, 3D and 360 dissection views, and an object oriented endoluminal display. In comparison to Colonoscopy, this tool has an advantage of depth penetration due to its 3D presentation capability. It is intended for use by Radiologists, Clinicians, and referring Physicians to process, render, review, archive and distribute colon image studies.

AutoBone is intended to facilitate segmentation of bony structures from abdominal and extremity CT Angiography data.

Advanced Lung Analysis is intended to provide an optimized non-invasive application to measure abnormalities in the lung (for example, nodules, lesions, etc.) from a set of Computed Tomography (CT) images. The software is designed to support the physician in confirming the presence or absence of physician identified lung lesions (e.g. nodules). The software allows measurement of volume over time using a consistent standardized measurement protocol, thus providing an estimation of the volume doubling time. ALA software allows analysis and displays statistics for nodule characterization all the different nodule types. ALA optional Digital Contrast Agent (DCA) module is an automated highlight feature for the visual identification of possible lesions. Digital Contrast Agent (DCA) is a 3D filter that produces images that highlight spherical (S) and cylindrical (C) anatomical regions, such as nodules, cysts, scars, and vessels. Images are made available to the physician to aid in characterization of suspicious nodules and thus, the patient management care decision process. ALA provides additional information to the physician and is intended to compliment diagnosis based on classical techniques.

Technology: The Centricity AW Suite Option employs the same functional scientific technology as its predicate devices.

Test Summary: The subject of this 510k is a software option for the Centricity PACS workstation. The Centricity PACS System complies with the voluntary standards as detailed in Section 12 Specific Standards and Guidance. The following quality assurance measures were applied to the development of the Centricity AW Suite Option:

- Risk Analysis
- Requirements Reviews
- Design Reviews

- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing

Conclusion: GE considers features of the Centricity AW Suite Option equivalent to those of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 30 2006

GE Healthcare Information Technologies
% Ms. Elizabeth Drew
Senior Project Engineer/510(k) Reviewer
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K061372
Trade/Device Name: Centricity® AW Suite Option
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 16, 2006
Received: May 17, 2006

Dear Ms. Drew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number (if known): Unknown; 510(k) filed on May 4, 2006

Device Name: Centricity® AW Suite Option

Indications for Use:
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X___ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061372